Hear now. And always

Cochlear®

ASX / MEDIA RELEASE

21st March 2014

FDA APPROVES COCHLEAR® NUCLEUS® HYBRID™ FOR SALE IN USA

Cochlear Limited (ASX: COH), the global leader in implantable hearing solutions, announced today that the US Food and Drug Administration (FDA) approved the Cochlear Nucleus Hybrid L24 Cochlear Implant System for commercial release.

This follows the unanimous recommendation for approval by the FDA Advisory Panel as disclosed on 11th November 2013.

This is a first of its kind system designed for the treatment of adults with severe to profound sensorineural hearing loss in the high frequencies, but who can still hear low-frequency sounds with or without a hearing aid.

The Nucleus Hybrid System combines acoustic amplification of low frequencies with the electrical stimulation of high frequencies in one device. It is designed to deliver patients superior quality and clarity of sound in even the most difficult hearing situations, especially hearing in noisy environments.

A copy of the FDA announcement is attached.

About Cochlear

Cochlear is the global leader in implantable hearing solutions. It has a dedicated global team of more than 2,700 people who deliver the gift of sound to those with hearing loss in over 100 countries. Its vision is to connect people, young and old, to a world of sound by offering life enhancing hearing solutions.

The Cochlear promise of "Hear now. And always" embodies the company's commitment to providing its recipients with their best possible hearing performance today and for the rest of their lives. For over 30 years Cochlear has helped hundreds of thousands of people either hear for the first time or reconnect them to their families, friends, workplaces and communities.

For more information, visit www.Cochlear.com.

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U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

FDA NEWS RELEASE

For Immediate Release: March 20, 2014
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FDA approves first implantable hearing device for adults with a certain kind of hearing loss

The U.S. Food and Drug Administration today approved the first implantable device for people 18 and older with severe or profound sensorineural hearing loss of high-frequency sounds in both ears, but who can still hear low-frequency sounds with or without a hearing aid. The Nucleus Hybrid L24 Cochlear Implant System may help those with this specific kind of hearing loss who do not benefit from conventional hearing aids.

Sensorineural hearing loss is the most common form of hearing loss and occurs when there is damage to the inner ear (cochlea). It may be caused by aging, heredity, exposure to loud noise, drugs that are toxic to the inner ear (e.g., antibiotics), and certain other illnesses. People with severe or profound sensorineural hearing loss of high-frequency sounds may have difficulty hearing faint sounds, understanding people with higher-pitched voices, hearing certain speech sounds, and, in some cases, hearing high-pitched emergency vehicle sirens or common safety alarms, such as smoke detectors.

"Hearing loss greatly impacts the education, employment, and well-being of many Americans," said Christy Foreman, director of the Office of Device Evaluation at the FDA's Center for Devices and Radiological Health. "This device may provide improved speech recognition for people with this kind of hearing loss, who have limited treatment options."

The Nucleus Hybrid L24 Cochlear Implant System combines the functions of a cochlear implant and a hearing aid. This electronic device consists of an external microphone and speech processor that picks up sounds from the environment and converts them into electrical impulses. The impulses are transmitted to the cochlea through a small bundle of implanted electrodes, creating a sense of sound that the user learns to associate with the mid- and high-frequency sounds they remember. The hearing aid portion of the device is inserted into the outer ear canal like a conventional hearing aid, and can amplify sounds in the low-frequency range.

The agency evaluated a clinical study involving 50 individuals with severe to profound high-frequency hearing loss who still had significant levels of low-frequency hearing. The individuals were tested before and after being implanted with the device. A majority of the patients reported statistically significant improvements in word and sentence recognition at six months after activation of the device compared to their baseline pre-implant performance using a conventional hearing aid. The device also underwent non-clinical testing, which included the electrical components, biocompatibility and durability of the device.

Of the 50 individuals participating in the study, 68 percent experienced one or more anticipated adverse events, such as low-frequency hearing loss, tinnitus (ringing in the ear), electrode malfunction and dizziness. Twenty-two developed profound or total low-frequency hearing loss in the implanted ear, six of whom underwent an additional surgery to replace the Nucleus Hybrid L24 Cochlear Implant System with a standard cochlear implant.

While the risk of low-frequency hearing loss is of concern, the FDA determined that the overall benefits of the device outweigh this risk for those who do not benefit from traditional hearing aids. Prospective patients should carefully discuss all benefits and risks of this new device with their physicians. The device is intended for use on one ear only.

The Nucleus Hybrid L24 Cochlear Implant System is manufactured by Cochlear Ltd., headquartered in New South Wales, Australia.

For more information:
FDA: **Medical Devices (/MedicalDevices/default.htm)**
NIH: **National Institute on Deafness and Other Communication Disorders: Cochlear Implants (http://www.nidcd.nih.gov/health/hearing/pages/coch.aspx)**

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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